AUG 4 2000

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510(k) SUMMARY

Invacare Corporation's
Model 9000 Pediatric Manual Wheelchair

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
PO Box 4028
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Edward A. Kroll
Director, TQM and Regulatory Affairs

Date Prepared: July 18, 2000

Name of Device and Name/Address of Sponsor

Model 9000 Pediatric Manual Wheelchair

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2028
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name

Wheelchair

Classification Name

Wheelchair, Mechanical

Predicate Devices:
Invacare Corporations' Action Jr. Pediatric Wheelchair (K914553) and Incorporation's Action Comet Pediatric Wheelchair (K934646).

Intended Use:
The intended use of the Invacare Model 9000 Pediatric Manual Wheelchair is to provide mobility to persons, primarily children that may be limited to a sitting position.

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Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Model 9000 Pediatric Manual Wheelchair manually operated, used propelled mechanical wheelchair. Its' intended function and use is to provide mobility to persons, primarily children, that may be limited to a sitting position.

The product consists primarily of a steel frame, large rear wheels with hand rims for propelling the chair, and smaller front pivoting casters for steering and turning. The product is a lightweight, everyday wheelchair for both indoor and outdoor use. It is a folding, or non-rigid type of wheelchair, which is designed for use by pediatric patients (ages 3 through 14) that weigh less than 150 lbs.

The frame is constructed of round, steel tubing that is welded. It is intended for use as a temporary, or short term wheelchair, for those pediatric patients that may be undergoing rehabilitation as a result of injury, surgery, or temporary impairment of some sort, as opposed to those that may be permanently handicapped, and require long term mobility assistance.

B. Substantial Equivalence

Products which are substantially equivalent to these devices are Invacare Corporations' Action Jr. Pediatric Wheelchair (K914553) and Incorporation's Action Comet Pediatric Wheelchair (K934646). Each of these products are manually operated, self propelled manual wheelchairs with the same intended function and use which is to provide mobility to persons, primarily children that may be limited to a sitting position. All products consist basically of a mechanical frame to support the wheelchair, larger rear wheels with hand rims for propelling the wheelchair, and smaller front pivoting casters for steering and turning.

PERFORMANCE DATA

The Invacare Model 9000 Pediatric Manual Wheelchair, meets the applicable performance requirements specified in the Rehabilitation Society of North America (RESNA) Standard ANSI/RESNA WC/Vol.1-1998 "Requirements and Test Methods for Wheelchairs (Including Scooters). The upholstery meets CAL 117 Standard for flame retardancy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Mr. Edward A. Kroll
Director, TQM and Regulatory Affairs
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036-2125

Re: K002170
Trade Name: Model 9000 Pediatric Manual Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: July 18, 2000
Received: July 19, 2000

Dear Mr. Kroll:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Diane R. Lochner.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~TBD~~ K002170

Device Name: *Model 9000 Pediatric Manual Wheelchair*

Indications For Use:
The intended use of the Invacare Model 9000 Pediatric Manual Wheelchair is to provide mobility to persons, primarily children that may be limited to a sitting position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002170

Prescription Use _____ **OR** **Over-The-Counter Use** ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)